



**WISCONSIN HOSPITAL  
ASSOCIATION**

**SUMMARY OF THE FINAL  
CALENDAR YEAR 2009  
MEDICARE HOSPITAL  
OUTPATIENT RULE**

**November 2008**

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# I. Overview

The Centers for Medicare and Medicaid Services published the final Medicare Outpatient Prospective Payment System rule for CY 2009 in the November 18, 2008 *Federal Register*. Changes are effective January 1, 2009 unless otherwise noted. This document provides an overview of the final rule. Additional information regarding the OPSS is available on the CMS Web site at <http://www.cms.hhs.gov/HospitalOutpatientPPS/>.

Note: Text in italics is extracted from the November 18, 2008 *Federal Register*.

## Major Provisions of the Final Rule:

- **Marketbasket Update Factor:** The final CY 2009 APC rates will include a full marketbasket update of 3.6 percent for CY 2009. Hospitals that were not compliant with the outpatient quality reporting requirements for CY 2008 will receive the marketbasket update minus 2.0 percentage points. The conversion factor will increase from \$63.694 in CY 2008 to \$66.059 in CY 2009, which includes a positive budget neutrality adjustment of 0.1 percent.
- **Outliers:** The outlier fixed-dollar threshold will increase from \$1,575 in CY 2008 to \$1,800 in CY 2009. Outlier payments are provided when the cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus the \$1,800 fixed-dollar threshold.
- **Quality Measures:** CMS is adopting its proposal to increase the number of outpatient quality measures that hospitals must report from seven to eleven in CY 2009. Hospitals that fail to report the eleven measures in CY 2009 will receive a reduction of 2.0 percentage points to the full marketbasket update in CY 2010. The four additional measures focus on imaging efficiency. CMS will continue to consider eighteen additional outpatient quality measures for future years' reporting.
- **Validation of Quality Reporting:** CMS is implementing a voluntary quality data validation approach for CY 2010, beginning with encounters from January 2009, the results of which will not affect the CY 2010 payment update for any hospital
- **Composite Ambulatory Payment Classification (APC) Groups:** CMS is increasing the number of composite APCs from five to ten for CY 2009. Composite APCs provide a single payment when a specified combination of procedure codes are provided in a single patient encounter, rather than paying for each service individually. The additional five composite APCs cover multiple imaging services.
- **Type B Emergency Department Visits:** Type B emergency departments (ED) offer emergency level services but are not open "24/7." Currently, these services are paid under clinic APCs. CMS is creating four new APCs for Type B ED visits. In addition, Level 5 Type B ED visits will be assigned to the same APC as Level 5 Type A visits. Based on data collected over the past few years for the Type B ED visits, CMS' analysis shows that they are more expensive than clinic visits but less costly than an emergency visit.
- **Drugs and Pharmacy Overhead:** CMS is **not** adding two new cost centers within the Medicare cost report for hospitals to report drugs with high and low pharmacy overhead costs.

## II. Ambulatory Payment Classification Payments

### Conversion Factor

*Federal Register* pages 68584 – 68585

**Background:** Outpatient payment rates are determined by multiplying the relative weight for an APC by the conversion factor.

**CMS' Final Rule:** *"The market basket increase update factor of 3.6 percent for CY 2009, the required wage index budget neutrality adjustment of approximately 1.0013, and the adjustment of*

*0.02 percent of projected OPSS spending for the difference in the pass-through set aside resulted in a full market basket conversion factor for CY 2009 of \$66.059.*

For hospitals that did not meet the Hospital Outpatient Quality Data Reporting Program (HOP QDRP) requirements for CY 2008, CMS will apply a reduction of 2.0 percentage points to the CY 2009 marketbasket update.

## **Wage Index Adjustment**

*Federal Register pages 68585 - 68587*

**Background:** To account for geographic differences, the labor portion of the conversion factor (60 percent) is adjusted by the hospital wage index. Currently, CMS applies the wage indexes used for the Inpatient Prospective Payment System (IPPS) to the OPSS conversion factor. These wage indexes also apply to Tax Equity Fiscal Responsibility Act of 1982 (TEFRA) hospitals that participate in OPSS, but not in the IPPS.

**CMS' Proposal:** For CY 2009, CMS proposed to use the final federal fiscal year (FFY) 2009 IPPS wage indices for OPSS payments. The proposed FFY 2009 IPPS wage indexes include “. . . a state-level rural floor and imputed floor budget neutrality adjustment applied to the wage index.”

In addition, CMS proposed “. . . to continue our policy in CY 2009 to allow non-IPPS hospitals paid under the OPSS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county.”

**CMS' Final Rule:** CMS is finalizing its proposal without modification for CY 2009.

**NOTE:** On July 15, 2008, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) provided an extension of 508 reclassifications through September 30, 2009, which also applies to OPSS wage indexes. On October 1, 2009, hospitals with 508 Wage Index reclassifications will revert back to receiving the Wage Index they would have received prior to passage of the MIPPA.

## **Rural Sole Community Hospital (SCH) Adjustment**

*Federal Register page 68590*

**CMS' Proposal:** For CY 2009, CMS proposed “. . . to continue our current policy of a budget-neutral 7.1 percent payment increase for rural SCHs, including EACHs, for all services and procedures paid under the OPSS, excluding drugs, biologicals, and services paid under the pass-through payment policy.”

**CMS' Final Rule:** CMS is finalizing its proposal without modification for CY 2009.

## **Transitional Corridor Payments**

*Federal Register pages 68589 - 68590*

**Background:** When the OPSS was implemented, transitional corridor payments were established to provide relief to hospitals that would receive less in payments under the OPSS methodology than they would have received under the prior payment system. Rural hospitals with 100 or fewer beds, cancer hospitals, and children's hospitals were held harmless and paid the full amount of the difference between the OPSS and the prior payment system. Other hospitals were eligible for partial relief.

For most hospitals, the transitional corridor payments were set to expire on December 31, 2003. The Medicare Modernization Act of 2003 (MMA) extended transitional corridor payments through December 31, 2005 for rural hospitals with 100 or fewer beds and provided transitional corridor payments during the same period for SCHs located in rural areas. The Deficit Reduction Act of 2007 (DRA) further extended

transitional corridor payments, phasing them out on a percentage basis, through December 31, 2008 for rural hospitals having 100 or fewer beds that are not SCHs (SCHs received a 7.1 percent add-on beginning in CY 2006; see “Rural Sole Community Hospital Adjustment” section above). Cancer hospitals and children’s hospitals are permanently held harmless from the impact of the OPSS.

**CMS’ Proposal:** Beginning January 1, 2009, “. . . rural hospitals having 100 or fewer beds that are not SCHs will no longer be eligible for hold harmless TOPs, in accordance with section 5105 of Pub. L. 109-171.”

**CMS’ Final Rule:** On July 15, 2008, MIPPA was signed into law which over-rode CMS’ proposal and extends the transitional payments for rural hospitals and SCHs with 100 or fewer beds through December 31, 2009.

## **Cost Outliers**

*Federal Register* pages 68591 - 68594

**Background:** OPSS outlier payments are provided for individual services or procedures with extraordinarily high costs compared to the payment rates for their APC group. For CY 2008, the outlier threshold is met when the cost of a service or procedure exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a \$1,575 fixed-dollar threshold. This dual test is intended to eliminate outlier payments for low-cost services and provide higher outlier payments for more expensive procedures. Currently, the projected target for aggregate outlier payments is set at 1.0 percent of aggregate total OPSS payments.

CMS pays 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the fixed-dollar threshold are met.

**CMS’ Proposal:** For CY 2009, CMS proposed “. . . that the hospital outlier threshold be set so that outlier payments would be triggered when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus an \$1,800 fixed-dollar threshold.”

*“For CY 2009, we are proposing to continue our policy of setting aside 1.0 percent of aggregate total payments under the OPSS for outlier payments. We are proposing that a portion of that 1.0 percent, specifically 0.07 percent, would be allocated to CMHCs for partial hospitalization program outlier payments.”*

**CMS’ Final Rule:** CMS is finalizing its proposed rule without modification for CY 2009. CMS estimates that “. . .this threshold will allocate 0.12 percent of outlier payments to CMHC’s for PHP outlier payments.”

## **Cost Outlier Reconciliation**

*Federal Register* pages 68594 - 68599

**Background:** In order for an OPSS claim to qualify for an outlier payment, the procedure’s cost must be significantly higher than the APC payment. Provider-specific cost-to-charge ratios (CCRs) are used to estimate a hospital’s costs from billed charges. Currently, these CCRs are developed using the most recent settled or tentatively settled cost report for each facility. CMS states that, due to the current time lag between CCRs developed from the latest settled cost report and current charges, creates the potential for hospitals to set charges higher to render an inappropriately high cost.

**CMS’ Proposal:** For CY 2009, CMS proposed to implement a reconciliation process similar to the IPPS process. *“Following current IPPS outlier policy, these thresholds would include a measure of acceptable percent change in a hospital’s or CMHC’s CCR and an amount of outlier payment involved. We are further proposing that when the cost report is settled, reconciliation of outlier payments would be based on the overall CCR calculated based on the ratio of costs and charges computed from the cost report at the time the*

*cost report coinciding with the service dates is settled. Reconciling these outlier payments would ensure that the outlier payments made are appropriate and that final outlier payments reflect the most accurate cost data.”*

*“Similar to the IPPS, we also are proposing to adjust the amount of final outlier payments determined during reconciliation for the time value of money . . . . Outlier payments would be subject to an adjustment to account for the value of the money for the time period in which the money was inappropriately held by the hospital or CMHC. This would also apply where outlier payments were underpaid. In those cases, the adjustment would result in additional payments to hospitals or CMHCs.”*

**CMS’ Final Rule:** CMS is adopting the outlier reconciliation policy as proposed “*. . . for each hospital and CMHC for services furnished during cost reporting periods beginning in CY 2009, and we are including an adjustment for the time value of money.*”

## **Calculation of CCRs**

*Federal Register pages 68519 - 68527*

**Background:** Since the inception of the OPSS, there has been concern about the OPSS cost-based weights’ “charge compression” and the distortion that could be caused by the lower charge mark-up that could be applied to higher-cost services. In August 2006, CMS contracted with RTI International to study charge compression, but limited the study to the IPPS relative weights. Subsequently, in August 2007, CMS contracted with RTI to evaluate the OPSS relative weights. The July 2009 RTI final report, *Refining Cost to Charge Ratios for Calculating APC and DRG Relative Payment*, is available on the RTI Web site at <http://www.rti.org>

**CMS’ Proposal:** RTI made eight recommendations specific to non-IPSS that include short-term and long-term accounting changes to the cost report. “*Given the magnitude and scope of impacts on APC relative weights that would result from adopting both accounting and statistical changes . . . we are not proposing to adopt any short-term adjustments to OPSS payment rate calculations.*”

**CMS’ Final Rule:** CMS is **not** adopting any changes to the cost report for CY 2009. However, “*...CMS continues to examine ways in which it can improve the cost reporting process. We have already implemented the minor change in the cost reporting software by imposing fixed descriptions on nonstandard cost centers. We also plan to add the new nonstandard cost centers for Cardiac Rehabilitation, Hyperbaric Oxygen Therapy, and Lithotripsy, as well as potentially a nonstandard cost center like Patient Education...when we revise the Medicare hospital cost report form.*”

## **Recalibration of APC Weights**

*Federal Register pages 68511 - 68519*

**Background:** CMS is required to review and revise the APC relative payment weights at least annually. The APC relative weights are based on the median hospital costs for services in the APC groups.

**CMS’ Proposal:** For CY 2009, CMS proposed “*. . . to recalibrate the relative payment weights for each APC based on claims and cost report data for outpatient services. We are proposing to use the most recent available data to construct the database for calculating APC group weights. For the purpose of recalibrating the proposed APC relative payment weights for CY 2009, we used approximately 130 million final action claims for hospital outpatient department (HOPD) services furnished on or after January 1, 2007, and before January 1, 2008.*”

**CMS' Final Rule:** CMS is adopting its proposal without modification for CY 2009. CMS "...used approximately 140 million final action claims for hospital outpatient department (HOPD) services furnished on or after January 1, 2007 and before January 1, 2008."

### III. Encounter-Based and Episode-Based Payments

For OPPS payments paid under APCs, packaging occurs when the payments for minor, ancillary services associated with a significant procedure are packaged into a single payment for the procedure. Bundling (or Composite APCs) occurs when payments for multiple significant procedures related to an outpatient encounter or to an episode of care are bundled into a single unit of payment. CMS believes that packaging and bundling payments for multiple interrelated services into a single payment creates incentives for providers to furnish services as efficiently as possible.

Prior to CY 2008, APC groups reflected a modest degree of packaging, including packaged payment for minor ancillary services, inexpensive drugs, medical supplies, implantable devices, capital-related costs, operating and recovery room use, and anesthesia services.

In CY 2008, CMS expanded its packaging and bundling of services to create incentives for hospitals to monitor and adjust the volume and efficiency of services delivered. Over time, CMS expects to contain growth in volume and spending by moving away from service specific-based payments and creating more encounter-based APCs that pay a single rate when a certain combination of procedure codes are reported on the same date of service.

#### Composite APCs

*Federal Register* pages 68550 - 68569

**Background:** In CY 2008, CMS adopted five composite APCs that provide a single, bundled payment when a specified combination of Healthcare Common Procedure Coding System (HCPCS) codes are reported on the same date of service, rather than paying for each service individually. They are as follows:

- APC 8000—Cardiac Electrophysiologic Evaluation and Ablation Composite
- APC 8001—Low Dose Rate (LDR) Prostate Brachytherapy Composite
- APC 8002—Level I Extended Assessment and Management Composite
- APC 8003—Level II Extended Assessment and Management Composite
- APC 0034—Mental Health Services Composite

**CMS' Final Rule:** CMS will continue to include the five composite APCs introduced in CY 2008. CMS is also adopting as final its proposal to add HCPCS code G0384 (Level 5 hospital emergency department visit provided in a type B emergency department) to the eligibility criteria for payment of composite APC 8003.

#### Multiple Imaging Composite APCs

**Background:** Currently, CMS pays the full APC payment for each imaging service on a claim, regardless of how many procedures are performed during a single session using the same imaging modality or whether the procedures are performed on contiguous body areas.

Per recommendations from the Medicare Payment Advisory Commission (MedPAC) in CY 2006, CMS proposed a payment reduction policy for multiple imaging procedures performed on contiguous body areas. In doing so, CMS proposed to apply a payment reduction of 50 percent for 11 designated imaging families for certain second and subsequent imaging procedures performed during the same session. However, based on comments received and due to inefficiencies in CMS' cost methodology, CMS did not implement a multiple imaging payment reduction policy in CY 2006.

CMS did state that this issue could be revisited in future years to ensure that multiple imaging rates properly reflect the relative costs of initial and subsequent imaging procedures.

**CMS’ Proposal—Multiple Imaging Composite APCs:** For CY 2009, CMS proposed “. . . to utilize the three OPPS imaging families, . . . incorporating statutory requirements to differentiate OPPS payment for imaging services provided with contrast and without contrast as required by section 1833(t)(2)(G) of the Act, to create five multiple imaging composite APCs for payment in CY 2009.” The three imaging families are ultrasound, CT and CTA, and MRI and MRA.

**CMS’ Final Rule – Multiple Imaging Composite APCs:** CMS is finalizing its proposal without modification for CY 2009.

The five new composite APCs are:

Imaging Family	CY 2009 Composite APC
Ultrasound Composite	8004
CT and CTA without Contrast Composite	8005
CT and CTA with Contrast	8006
MRI and MRA without Contrast	8007
MRI and MRA with Contrast	8008

For a complete listing of the HCPCS codes that fall into the five proposed imaging APCs, refer to Table 8 on page 68566 in the *Federal Register*.

## Packaged Services

*Federal Register* pages 68570 - 68584

**Background:** In CY 2008, CMS expanded its packaging of services to create incentives for hospitals to monitor and adjust the volume and efficiency of services delivered. Over time, CMS intends to contain growth in volume and spending by moving away from service specific-based payments and creating more packaged APCs.

As an initial step towards creating larger payment groups for outpatient care in CY 2008, CMS began packaging payments for items and services in the following seven categories. Packaged services are not paid separately and instead are included in the payment for the primary diagnostic or therapeutic modality to which these items and services are typically ancillary or supportive.

- guidance services;
- image processing services;
- intraoperative services;
- imaging supervision and interpretation services;
- diagnostic radiopharmaceuticals;
- contrast media; and
- observation services.

In these cases, CMS assigns one of two status indicators to these HCPCS codes.

- CMS assigns a status indicator of “N” for procedures that changed from separately paid to unconditionally packaged. CMS always packages the cost of the procedure into the costs of the separately paid primary services with which they are billed.
- CMS assigns a status indicator of “Q” for procedures that changed from separately paid to

conditionally packaged. In this case, the procedure is either packaged or separately paid, depending on the services with which it is reported (refer to the “Status Indicator” section).

Most conditionally packaged HCPCS codes are assigned to only one of the conditionally packaged categories (refer to the “Status Indicator” section).

**CMS’ Proposal:** CMS proposed to assign “. . . CPT code 75635 (Computed tomographic angiography, abdominal aorta and bilateral iliofemoral lower extremity runoff, with contrast material(s), including noncontrast images, if performed, and image postprocessing) as both a “T-packaged code” and a component of composite APC 8006 (CT and CTA with Contrast Composite). We are proposing to assign this code status indicator “Q2” in Addendum B and “Q3” in Addendum M, to signify its dual treatment.”

CMS also proposed “. . . to package payment for HCPCS code G0332 (Services for intravenous infusion of immunoglobulin prior to administration (this service is to be billed in conjunction with administration of immunoglobulin)) for CY 2009.”

**CMS’ Final Rule:** CMS is finalizing its proposal without modification for CY 2009.

**NOTE:** A Packaging Subcommittee of the APC Panel was established to ensure that, in future years, packaging of HCPCS codes is done appropriately. This subcommittee will provide recommendations to the APC Panel that CMS can take under consideration for future outpatient policy changes.

**CMS’ Proposal:** CMS proposed to assign Current Procedural Terminology (CPT) code 36592 (Collection of blood specimen using established central or peripheral catheter, venous, not otherwise specified) to APC 0624 (Phlebotomy and Minor Vascular Access Device Procedures). “. . . we are proposing to change the packaged status of CPT code 36592 from unconditionally packaged to conditionally packaged, as an ‘STVX-packaged code,’ which is parallel to the proposed treatment of CPT code 36591.” Therefore, for CY 2009, CMS proposed to assign status indicator “Q1” to CPT 36592, which indicates that it is an “STVX-packaged code.”

**CMS’ Final Rule:** CMS is finalizing its proposal without modification for CY 2009.

**CMS’ Proposal:** For CY 2009, CMS proposed “. . . to treat CPT code 74305 (Cholangiography and/or pancreatography; through existing catheter, radiological supervision and interpretation) as a “T-packaged code” and assign it to APC 0263 (Level I Miscellaneous Radiology Procedures).”

**CMS’ Final Rule:** CMS is finalizing its proposal without modification for CY 2009.

## **Status Indicators**

*Federal Register* pages 68707 - 68710

**Background:** CMS assigns status indicators to HCPCS procedure codes to indicate whether a service is payable under the OPSS or another payment system. In addition, status indicators signal the particular OPSS policies that apply to the code.

For CY 2008, CMS assigned a status indicator of “Q” to procedures that would change from separately paid to conditionally packaged. In these cases, the procedure is either packaged or paid separately, depending on the services with which it is reported. There are two subsets of the special packaged codes for the purpose of payment:

- imaging supervision and interpretation special packaged codes are named “T-packaged” codes; and
- all other special packaged codes are referred to as “STVX-packaged” codes.

Payment for an HCPCS code with a status indicator of “Q” is packaged unless:

- the HCPCS code is not reported on the same day with a service that has a status indicator of “S,” “T,” “V,” or “X,” in which case it would be paid separately—CMS refers to this situation as “STVX-packaged;” or
- the HCPCS code is not reported on the same day with a service that has a status indicator of “T,” in which case it would be paid separately—CMS refers to this situation as “T-packaged.”

In addition, for CY 2008, CMS assigned a status indicator of “K” for brachytherapy source APCs.

**CMS’ Proposal:** For CY 2009, CMS proposed “. . . to replace current status indicator “Q” with three new separate status indicators: “Q1,” “Q2,” and “Q3.” We are proposing that status indicator “Q1” would be assigned to all “STVX-packaged codes;” status indicator “Q2” would be assigned to all “T-packaged codes;” and status indicator “Q3” would be assigned to all codes that may be paid through a composite APC based on composite-specific criteria or separately through single code APCs when the criteria are not met.”

“. . . we are proposing to use new payment status indicator “R” for all blood and blood product APCs and to use new payment status indicator “U” for all brachytherapy source APCs.”

**CMS’ Final Rule:** CMS is finalizing its proposal without modification for CY 2009.

For a complete listing of HCPCS codes and their applicable status indicators and APC assignments for CY 2009, refer to Addendum B.

## **IV. Reporting of Hospital Outpatient Quality Data**

*Federal Register* pages 68758 - 68781

The Medicare Improvements and Extension Act (MIEA) of 2006 required CMS, by CY 2009, to establish a quality reporting program specific to hospital outpatient care using standardized measures of care to receive the full annual update to the OPSS payment rate.

### **Reporting Requirements to Receive the Full OPSS Update**

**Background:** In CY 2008, CMS adopted seven outpatient quality measures that have been endorsed by the National Quality Forum (NQF) under the HOP QDRP. These outpatient measures include five emergency department-acute myocardial infarction (ED-AMI) measures and two Perioperative Care measures. To receive the full OPSS payment update for services, providers must submit data on the seven outpatient measures effective for hospital outpatient services furnished on or after April 1, 2008. Non-compliant providers in CY 2008 will receive the OPSS marketbasket conversion factor update reduced by 2.0 percentage points for all OPSS payments in CY 2009. In addition, CMS proposed to reduce the beneficiary payment for non-compliant hospitals in CY 2009.

### **CY 2009 HOP QDRP Program**

Currently, the following seven outpatient quality measures are reported:

ED-AMI-1	Aspirin at Arrival
ED-AMI-2	Median Time to Fibrinolysis
ED-AMI-3	Fibrinolytic Therapy Received within 30 Minutes of Arrival
ED-AMI-4	Median Time to Electrocardiogram (ECG)
ED-AMI-5	Median Time to Transfer for Primary PCI
PQRI #20	Perioperative Care: Timing of Antibiotic Prophalaxis
PQRI #21	Perioperative Care: Selection of Perioperative Antibiotic

**CMS' Proposal—HOP QDRP Quality Measures:** For CY 2009, CMS proposed the continued submission of data on the seven measures listed above with the inclusion of four new imaging measures (see below).

**Designation**

OP-8	MRI Lumbar Spine for Low Back Pain
OP-9	Mammography Follow-up Rates
OP-10	CT Abdomen - Use of Contrast Material
	CT Abdomen - Use of Contrast Material excluding calculi of the kidneys, ureter, and/or urinary tract
	CT Abdomen - Use of Contrast Material for diagnosis of calculi of the kidneys, ureter, and/or urinary tract
OP-11	Throax CT - Use of Contrast Material

The four imaging measures will be reported in CY 2009; non-compliance with these reporting requirements will be reflected in OPPS payments for CY 2010.

These new imaging measures are meant to promote efficient and high quality care, as MedPAC has expressed concern regarding the potential overuse of imaging services. These measures are claim-based determinations that can be calculated using Medicare Part B claims data, requiring no additional chart abstraction by facilities.

**CMS' Final Rule – HOP QDRP Quality Measures:** CMS will continue to require submission of the current seven measures and is adopting the four new imaging measures for CY 2009, as proposed.

Two of the imaging measures, OP-8 and OP-11 are NQF-endorsed.

**Participation Procedures and Requirements**

To participate in the HOP QDRP for CY 2009 and subsequent calendar years, hospitals must meet administrative and data collection/submission requirements. For the most part, these procedures and requirements mirror those currently in place under the IPPS Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program.

**Data Collection and Submission Requirements**

Currently, data are submitted through the QualityNet secure Web site at <http://www.qualitynet.org>. Submission deadlines are four months after the last day of each calendar quarter for measures finalized in the current OPPS final rule.

Submissions for first calendar quarter (January - March) of 2009 will be due August 1, 2009, and second calendar quarter (April - June) of 2009 will be due November 1, 2009. All OPPS submissions must be timely, complete, and accurate.

## **Validation Requirement**

CMS has not required data validation for CY 2009 payment update determinations. However, as discussed in the final OPSS rule for CY 2008, validation is intended to provide assurance of the accuracy of the hospital abstracted data.

**CMS' Proposal—Validation Requirement:** Starting with data reported in January 2009, CMS proposed “. . . to implement validation requirements that will apply beginning with the CY 2010 payment determinations.”

*“Specifically, we propose to randomly select per year, 50 patient episodes of care that a hospital successfully submitted to the OPSS Clinical Warehouse for the relevant time period and validate those data by requesting that the hospital send the supporting medical record documentation that corresponds to each selected episode to a CMS contractor within 30 calendar days of the date of the request.”*

Unlike the IPPS RHQDAPU program, CMS proposed “. . . to validate data from 800 randomly selected hospitals (approximately 20 percent of all participating HOP QDRP hospitals) each year. However, we note that because the 800 hospitals will be selected randomly, every HOP QDRP participating hospital will be eligible each year for validation selection.”

In summary, CMS will select 50 patient episodes of care from 800 randomly selected hospitals.

In addition, the proposed OPSS validation score calculation will be based on a percent agreement for each calculated clinical measure rather than for the individual data elements that would be calculated. The methodology for calculating the confidence interval under the HOP QDRP will be the same as currently utilized for the IPPS RHQDAPU program. *“We anticipate estimating the percent reliability based upon a review of submitted documentation and then calculating the upper 95 percent confidence limit for that estimate. If that upper limit is above the required 80 percent reliability threshold, we will consider the hospital's data ‘validated’ for payment update purposes for CY 2010.”*

**CMS' Final Rule – Validation Requirement:** CMS is **not** adopting their validation proposal, *“...but instead are adopting a voluntary test validation process for CY 2010.”* The results of this voluntary validation will not affect the CY 2010 payment update for any hospital. CMS is encouraging hospital participation to gain experience with the validation process. CMS plans *“...to propose a validation program for CY 2011 payment update in our CY 2010 OPSS/ASC proposed rule.”*

## **Reconsideration Procedures**

CMS has not implemented a reconsideration submission process for hospitals. CMS intends to implement a reconsideration process for HOP QDRP modeled after the reconsideration process implemented under the IPPS RHQDAPU program.

Failure to report on the 11 measures in CY 2009 will result in a payment reduction of 2.0 percentage points in CY 2010.

## **CY 2010 HOP QDRP Program**

### **Program Expansion**

**CMS' Final Rule – Program Expansion:** For CY 2010, CMS will continue to require submission of the seven current measures as well as the four new imaging measures.

## **Redesignation of Outpatient Quality Measures**

**CMS' Final Rule—Redesignation of Measures:** For CY 2010, CMS will re-designate the original seven HOP QDRP measures as follows:

<b>Current Designation</b>	<b>Proposed Designation</b>
ED-AMI-2	OP-1: Median Time to Fibrinolysis
ED-AMI-3	OP-2: Fibrinolytic Therapy Received Within 30 Minutes
ED-AMI-5	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
ED-AMI-1	OP-4: Aspirin at Arrival
ED-AMI-4	OP-5: Median Time to ECG
PQRI #20	OP-6: Timing of Antibiotic Prophylaxis
PQRI #21	OP-7: Prophylactic Antibiotic Selection for Surgical Patients

## **Administrative Requirements**

For hospitals to participate in the HOP QDRP, they are required to:

- Register on QualityNet;
- Name a QualityNet administrator; and
- Complete a Notice of Participation form.

Hospitals that did not participate or withdrew from participation in the CY 2009 HOP QDRP must submit a Notice of Participation form by January 31, 2009 in order to participate in the CY 2010 HOP QDRP.

## **Data Collection and Submission Requirements**

**CMS' Proposal—Data Collection:** For CY 2010, CMS proposed “. . . beginning with services furnished on or after January 1, 2009, hospitals that have five or fewer claims (both Medicare and non-Medicare) for any measure included in a measure topic in a quarter will not be required to submit patient level data for the entire measure topic for that quarter. However, the hospital would still be required to submit its aggregate measure population and sample size counts for the applicable measure topic as part of its quarterly data submission.”

**CMS Final Rule – Data Collection:** For CY 2010, CMS is adopting its proposal on data collection and submission requirements without modification.

## **Validation Requirement**

**CMS' Proposal:** For CY 2011 payment determination, CMS proposed alternatives for data validation:

- validate all participating hospitals using a random sample of five medical records per quarter;
- select targeted hospitals based on criteria designed to measure whether the data being reported by them raised a concern regarding accuracy; or
- a combination of two approaches discussed above.

*In addition, CMS proposed “. . . for CY 2011 to implement an on-line registration form and eliminate the paper form” (Notice of Participation).*

**CMS' Final Rule:** CMS has **not** adopted any of the alternatives for data validation for CY 2011.

For CY 2011, CMS is “. . .finalizing the use of an on-line registration form with the concomitant elimination for the paper form for the Notice of Participation requirement...”

## **Reconsideration and Appeals Procedures**

**CMS' Proposal:** For CY 2010, CMS proposed a “. . . mandatory reconsideration and appeals process that will apply to the CY 2010 payment decisions. In order to receive reconsideration of CY 2010 payment

decisions . . . hospitals must submit to CMS, via QualityNet, a Reconsideration Request form that will be made available on the QualityNet Web site.”

**CMS’ Final Rule:** CMS is adopting the “...HOP QDRP reconsideration and appeals process as proposed.”

## CY 2011 (and Subsequent Years) HOP QDRP Program

### Program Expansion

**CMS’ Proposal:** CMS proposed 18 additional measures within nine measure sets that could be adopted for use in CY 2011 and subsequent years. They are as follows:

Topic	Measure
Cancer	1 Radiation Therapy is Administered within 1 Year of Diagnosis for Women Under Age 70 Receiving Breast Conserving Surgery for Breast Cancer
	2 Adjuvant Chemotherapy is Considered or Administered within 4 Months of Surgery to Patients Under Age 80 with AJCC III Colon Cancer
	3 Adjuvant Hormonal Therapy for Patients with Breast Cancer
	4 Needle Biopsy to Establish Diagnosis of Cancer Precedes Surgical Excision/Resection
ED Throughput	5 Median Time from ED Arrival to ED Departure for Discharged ED Patients
Diabetes	6 Low Density Lipoprotein Control in Type 1 or 2 Diabetes Mellitus
	7 High Blood Pressure Control in Type 1 or 2 Diabetes Mellitus
Falls	8 Screening for Fall Risk
Depression	9 Antidepressant Medication During Acute Phase for Patients with New Episode of Major Depression
Stroke & Rehab	10 Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Reports
	11 Carotid Imaging Reports
Osteo	12 Communication with the Physician Managing Ongoing Care Post Fracture
	13 Screening or Therapy for Women Aged 65 Years and Older
	14 Pharmacologic Therapy
	15 Management Following a Fracture
Medication Reconciliation	16 Medication Reconciliation
Respiratory	17 Asthma Pharmacological Therapy
	18 Assessment of Mental Status for Community Acquired Pneumonia

**CMS’ Final Rule:** CMS has **not** adopted any of the proposed measures for CY 2011 and beyond. However, CMS “...will consider the recommended topic areas as we develop new quality measures for CY 2011 and subsequent calendar years.”

### **Health Care-Associated Conditions**

*Federal Register* pages 68781 - 68787

### IPPS Hospital-Acquired Conditions Payment Provision to the OPDS

**Background:** In 2005, Congress authorized CMS to adjust Medicare IPPS hospital payments to encourage the prevention of eight selected hospital-acquired conditions (HACs), based on the following criteria:

- high-cost, high-volume, or both;
- result in the assignment of a case to a Diagnosis Related Group (DRG) that has a higher payment when present as a secondary diagnosis; and
- could reasonably have been prevented through the application of evidence-based guidelines.

CMS has **not** adopted these conditions under the OPDS but plans to apply these strategies across the continuum of care for Medicare beneficiaries. CMS will refer to other settings across the continuum excluding inpatient as “health care-associated conditions.”

*“The implementation would be different for each setting, as each Medicare payment system is different, and the reasonable preventability through the application of evidence-based guidelines would vary for candidate conditions across the various care settings. However, alignment of incentives across settings carries an important goal for all of CMS’ VBP initiatives, including the hospital-acquired conditions payment provision.”*

**CMS’ Proposal:** For CY 2009, CMS did **not** propose “. . . new Medicare policy in this discussion of health care-associated conditions as they relate to the OPPS. Instead, we are seeking public comments on options and considerations, including statutory authority, related to extending the IPPS hospital-acquired conditions payment provision for hospitals to the OPPS. “

CMS states that, *“We believe that only a small number of the hospital-acquired conditions adopted in the FY 2008 IPPS final rule with comment period could potentially be applicable to the OPPS. These include:*

- *object left in during surgery;*
- *air embolism;*
- *blood incompatibility; and*
- *falls and trauma fractures, dislocations, intracranial injuries, crushing injuries, and burns.”*

*“We acknowledge that reporting even this short list of health care-associated conditions as a secondary diagnosis on a claim in order to attribute their occurrence to the HOPD encounter might present problems for hospitals, particularly for the conditions resulting from trauma or falls. Consequently, we are also seeking comment on whether or not we could assume that these conditions reported as secondary diagnoses on OPPS claims would have developed during the encounter or whether the reporting of POA indicator information should be required under the OPPS (and perhaps under every Medicare payment system) because POA data increase the utility of claims for analyzing the characteristics of a clinical encounter.”*

**CMS’ Final Rule:** At this time, CMS is **not** adopting any requirements for OPPS related to hospital-acquired conditions.

## **V. Transitional Pass-Through Payments**

### **Pass-Through Spending**

*Federal Register* pages 68632 - 68633

**Background:** The Balanced Budget Refinement Act of 1999 (BBRA) provides transitional pass-through payments for certain drugs, pharmaceuticals, biologicals, and medical devices. The cap on the total amount of pass-through spending is 2.0 percent of total OPPS payments. Estimated pass-through spending that does not exceed the 2.0 percent cap is returned to the conversion factor.

**CMS’ Proposal:** *“Because we estimate that pass-through spending in CY 2009 would not amount to 2.0 percent of total projected OPPS CY 2009 spending, we are proposing to return 1.93 percent of the pass-through pool to adjust the conversion factor . . . .”*

**CMS’ Final Rule:** CMS is *“...setting the applicable percentage limit at 2.0 percent of the total OPPS projected payments for CY 2009, consistent with our OPPS policy from CYs 2004 through 2008.*

CMS estimates that *“...pass-through spending in CY 2009 would not amount to 2.0 percent of total projected OPPS CY 2009 program spending.”*

The *“...final pass-through estimate for CY 2009 is \$33.3 million.”*

## Payment for Pass-Through Drugs, Biologicals, and Radiopharmaceuticals

*Federal Register* pages 68633 - 68641

**Background:** The law limits payments for pass-through drugs for between two and three years. It has been CMS' policy to remove drugs from pass-through status as quickly as possible and most are incorporated into the APC rates after two years.

The MMA requires pass-through drugs to be paid at the average sales price (ASP) + 6 percent for 2005 and thereafter, unless the drug or biological is covered under the Competitive Acquisition Program (CAP). In the latter case, the payment rate is equal to the average price for all competitive acquisition areas and the year established as calculated and adjusted by the Secretary of Health and Human Services (HHS). Therefore, for most cases, the pass-through payment amount for drugs and biologicals is equal to the difference between ASP + 6 percent and ASP + 4 percent (the applicable fee schedule portion associated with the drug or biological). The ASP methodology is based on data submitted by manufacturers and is updated quarterly.

Tables identifying the drugs and biologicals, both continuing and expiring, with pass-through status for CY 2009 are available in the *Federal Register* pages referenced above.

**CMS' Proposal:** CMS proposed no changes.

**CMS' Final Rule:** For CY 2009, CMS is expiring pass-through status for the 15 drugs and biologicals listed in Table 23 of the final rule, effective December 31, 2008. *"Packaged drugs and biologicals are assigned status indicator 'N' and drugs and biologicals that continue to be separately paid as nonpass-through products are assigned status indicator 'K'."*

*"The drugs and biologicals that are continuing pass-through status or have been granted pass-through status as of January 2009 for CY 2009 are displayed in Table 2..."* of the final rule.

CMS notes that *"...the Part B drug CAP program has been postponed for CY 2009...Therefore, there will be no effective Part B drug CAP rate for pass-through drugs and biologicals as of January 1, 2009."*

## Pass-Through Devices

*Federal Register* pages 68633 - 68641

**Background:** The law limits payments for pass-through devices for between two and three years. It has been CMS' policy to remove devices from pass-through status as quickly as possible and most are incorporated into the APC rates after two years. For devices, the pass-through payment equals the amount by which the hospital's charges, adjusted to cost, exceeds the OPPS payment rate associated with the device.

Currently, there are two categories (C1821 and L8690) that are eligible for transitional pass-through payments as of January 1, 2007 through December 31, 2008.

As required by law, CMS deducts from the pass-through payments for the identified devices an amount that reflects the portion of the APC payment amount that CMS determines is associated with the cost of the device, referred to as the APC offset amount.

**CMS' Proposal:** For CY 2009, CMS proposed to *"...discontinue pass-through payment for device category codes C1821 and L8690."* *"We currently have no established device categories eligible for pass-through payment that are continuing into CY 2009..."*

In addition, CMS is proposing *"...to continue our established policies for calculating and setting the APC offset amounts for each device category eligible for pass-through payment. We are also proposing to continue to review each new device category on a case-by-case basis, to determine whether device costs associated with the new category are packaged into the existing APC structure. If device costs packaged*

*into the existing APC structure are associated with the new category, we would deduct the APC offset amount from the pass-through payment for the device category.”*

**CMS’ Final Rule:** CMS “...will discontinue pass-through payment for HCPCS device category codes C1821 and L8690.” There are **no** device categories eligible for pass-through status in CY 2009.

In addition, CMS will continue their “...established policies for calculating and setting the APC offset amounts for each device category eligible for pass-through payment, and for reviewing each new device category on a case-by-case basis, to determine whether device costs associated with the new category are packaged into the existing APC structure.”

CMS will publish a list of all procedural APCs with the CY 2009 portions of the APC payment amounts that they determine to be associated with the cost of devices at their website.

## **VI. Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status**

### **Reporting of Pharmacy Overhead Charges**

*Federal Register* pages 68649 - 68651

**Background:** Currently, the payment methodology provides for a single bundled payment representing average hospital acquisition costs and associated pharmacy overhead costs. However, according to a survey done by MedPAC on hospital charging practices, hospitals set charges for drugs, biologicals, and radiopharmaceuticals high enough to reflect their pharmacy handling costs as well as their acquisition costs.

**CMS’ Proposal:** For CY 2009, CMS proposed “. . . to continue our policy of making a combined payment for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals at an equivalent average ASP-based amount calculated based on our standard methodology of estimating drug costs from claims.”

*“. . . we also propose to break the single standard cost center 5600 into two standard cost centers, Drugs with High Overhead Costs Charges to Patients and Drugs with Low Overhead Costs Charged to Patients, to reduce the reallocation of pharmacy overhead from expensive to inexpensive drugs and biologicals when setting an equivalent average ASP-based payment amount in the future.”*

**CMS’ Final Rule:** CMS is **not** finalizing its proposal to “...split the single standard drug cost center into two cost centers. Instead, we will continue to explore other potential approaches to improving out drug cost estimation to improve payment accuracy...”

### **Payment for Non Pass-Through Drugs**

*Federal Register* pages 68641 - 68645

**CMS’ Proposal:** “. . . we are proposing to pay separately for payable drugs and biologicals under the CY 2009 OPPS at ASP + 4 percent . . .” as opposed to ASP + 5 percent in CY 2008.

**CMS’ Final Rule:** CMS is finalizing its proposal without modification for CY 2009.

## Payment for Drugs, Biologicals, and Radiopharmaceuticals—Packaging Criteria

*Federal Register* page 68642

**Background:** The costs of drugs, biologicals, and radiopharmaceuticals are generally packaged into the APC rate for their related procedures or services, unless they are determined to be relatively expensive or are rarely used. Items such as single indication “orphan” drugs, certain vaccines, and blood and blood products are excluded from the packaging policy. In addition, oral and injectable forms of 5HT3 anti-emetic products are exempt.

Packaging status is based on a comparison of CMS-calculated per-day cost of the item to a packaging threshold. The packaging threshold for establishing separate APCs for drugs and biologicals was set at \$50 per administration during CYs 2005 and 2006. For CY 2007, CMS finalized a policy to adjust the packaging threshold for inflation using the Producer Price Index (PPI), resulting in a packaging threshold of \$55. For CY 2008, the packaging threshold was set at \$60.

**CMS’ Proposal:** “. . . we are proposing a packaging threshold for CY 2009 of \$60.”

*“Following the CY 2007 methodology for CY 2009, we used updated fourth quarter moving average PPI levels to trend the \$50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2009 and again rounded the resulting dollar amount (\$61.25) to the nearest \$5 increment, which yielded a figure of \$60.”*

**CMS’ Final Rule:** CMS is finalizing its proposal without modification for CY 2009. Oral and injectable forms of 5HT3 antiemetic products continue to be exempt.

**NOTE:** Due to the July 15, 2008 passage of MIPPA, hospital claims can no longer be used to establish the packaging status of therapeutic radiopharmaceuticals. Instead, all radiopharmaceuticals will be paid separately in CY 2009 at hospital charges adjusted to cost.

## Payment for Radiopharmaceuticals

*Federal Register* pages 68632 - 68638

**Background:** Per the MMA, radiopharmaceuticals are exempt from ASP pricing. Because radiopharmaceuticals are considered specified covered outpatient drugs, payments must be made at average acquisition cost as determined by the HHS Secretary and subject to any adjustment for overhead costs. However, CMS does not have ASP data for radiopharmaceuticals. Therefore, for CYs 2006 and 2007, CMS paid for radiopharmaceuticals at charges reduced to cost using the overall hospital CCR. In CY 2007, CMS stated its intention to develop a suitable prospective payment methodology for radiopharmaceutical products paid under the OPSS in future years, beginning in CY 2008.

In the CY 2008 OPSS final rule, CMS expanded its general packaging approach in a desire to move the OPSS toward more encounter-based and episode-based payments in the future. Based on this approach and CMS’ belief that therapeutic radiopharmaceuticals are distinct from diagnostic, CMS adopted a prospective payment for therapeutic radiopharmaceuticals using mean costs derived from the most current claims data, where the costs are determined using the standard methodology of applying hospital-specific departmental CCRs to radiopharmaceutical charges, defaulting to hospital-specific overall CCRs only if appropriate departmental CCRs are unavailable.

**CMS’ Proposal—Diagnostic Radiopharmaceuticals:** For CY 2009, CMS proposed “. . . to continue packaging payment for all non pass-through diagnostic radiopharmaceuticals and contrast agents regardless of their per day cost . . . .”

**CMS’ Final Rule:** CMS is adopting the above CY 2009 proposal without modification. Additionally, they “...are finalizing our proposal to continue to identify diagnostic radiopharmaceuticals specifically as those

Level II HCPCS codes that include the term ‘diagnostic’ along with a radiopharmaceutical in their long code descriptors, and therapeutic radiopharmaceuticals as those Level II HCPCS codes that include the term “therapeutic” along with a radiopharmaceutical in their long code descriptors...” originally proposed in CY 2008..

**CMS’ Proposal—Therapeutic Radiopharmaceuticals:** For CY 2009, CMS proposed that “*For therapeutic radiopharmaceuticals where ASP information is submitted through the established ASP process by all manufacturers of the specific therapeutic radiopharmaceutical, we would provide payment for the average acquisition and associated handling costs of the therapeutic radiopharmaceutical at the same relative ASP-based amount (proposed at ASP + 4 percent for CY 2009) that we would pay for separately payable drugs and biologicals in CY 2009 under the OPSS.*”

Furthermore, “*if sufficient ASP information is not submitted or appropriately certified by the manufacturer for a given calendar year quarter, then for that quarter we are proposing that the OPSS would provide a prospective payment based on the mean cost from hospital claims data . . . .*” Refer to Table 25 on page 41496 of the *Federal Register*.

**CMS’ Final Rule:** The July 15, 2008 passage of MIPPA further extends the payment period for therapeutic radiopharmaceuticals based on hospital’s charges adjusted to cost through December 31, 2009. CMS will continue to consider its proposal for CY 2010.

## **Payment for Blood Clotting Factors**

*Federal Register* page 68659

**Background:** For CY 2008, CMS provides payment for blood clotting factors at ASP + 5 percent plus an additional payment for the furnishing fee. The furnishing fee is currently \$0.158 per unit. The furnishing fee provided under the OPSS is updated each year in the Medicare Physician Fee Schedule (MPFS) final rule.

**CMS’ Proposal:** For CY 2009, CMS proposed “. . . to pay for blood clotting factors at ASP + 4 percent . . . and to continue our policy for payment of the furnishing fee using an updated amount for CY 2009.”

**CMS’ Final Rule:** CMS is finalizing its proposal without modification for CY 2009.

## **Payment for Non Pass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes, but Without OPSS Hospital Claims Data**

*Federal Register* pages 68663 - 68666

**Background:** For CYs 2005, 2006, and 2007, CMS paid separately for new drugs, biologicals, and radiopharmaceuticals with HCPCS codes, but which did not have pass-through status at a rate that was equivalent to the payment they received in the physician office setting (ASP + 6 percent). In CY 2008, CMS paid for these at ASP + 5 percent.

**CMS’ Proposal—New Drugs and Biologicals:** For CY 2009, CMS proposed “. . . to provide payment for new drugs and biologicals with HCPCS codes, but which do not have pass-through status and are without OPSS hospital claims data, at ASP + 4 percent, consistent with the CY 2009 proposed payment methodology for other separately payable non pass-through drugs and biologicals.”

“. . . in the absence of ASP data, we are proposing, for CY 2009, to continue the policy we implemented beginning in CY 2005 of using the WAC for the product to establish the initial payment rate for new non pass-through drugs and biologicals with HCPCS codes, but which are without OPSS claims data. However, we note that if the WAC is also unavailable, we would make payment at 95 percent of the product’s most recent AWP.”

*“We are also proposing to assign status indicator “K” to HCPCS codes for new drugs and biologicals for which we have not received a pass-through application.”*

**CMS’ Proposal—New Diagnostic Radiopharmaceuticals:** For CY 2009, CMS proposed “. . . to continue packaging payment for all new non pass-through diagnostic radiopharmaceuticals in CY 2009.”

**CMS Final Rule:** CMS is finalizing its proposal without modification for CY 2009.

**CMS’ Proposal—New Therapeutic Radiopharmaceuticals:** For CY 2009, CMS proposed “. . . to base payment for new therapeutic radiopharmaceuticals with HCPCS codes as of January 1, 2009, but which do not have pass-through status, on the WACs for these products if ASP data for these therapeutic radiopharmaceuticals are not available. If the WACs are also unavailable, we would make payment for new therapeutic radiopharmaceuticals at 95 percent of their most recent AWP . . . .”

*“. . . we are proposing to assign status indicator “K” to HCPCS codes for new therapeutic radiopharmaceuticals for which we have not received a pass-through application.”*

**CMS’ Final Rule:** The proposal on therapeutic radiopharmaceuticals is overridden by the July 15, 2008 passage of MIPPA. This act requires payment for therapeutic radiopharmaceuticals based on hospital’s charges adjusted to cost through December 31, 2009.

**CMS’ Proposal—Non Pass-Through Drugs and Biologicals Payable in CY 2007 and/or CY 2008 without CY 2007 Claims Data:** For CY 2009, CMS is proposing “. . . to package items for which we estimate the per administration cost to be less than or equal to \$60, which is the general packaging threshold that we are proposing for drugs, biologicals, and therapeutic radiopharmaceuticals in CY 2009.”

*“We are proposing to pay separately for items with an estimated per administration cost greater than \$60 (with the exception of diagnostic radiopharmaceuticals and contrast agents . . .) in CY 2009.”*

*“We are proposing that the CY 2009 payment for separately payable items without CY 2007 claims data would be based on ASP + 4 percent . . . .”*

**CMS’ Final Rule:** CMS is finalizing its proposal without modification for CY 2009.

For a list of the non pass-through drugs and biologicals without available CY 2007 claims data, refer to Table 30 on page 68664 of the *Federal Register*.

## **VII. APC Group Changes**

*Federal Register* pages 68707 - 68711

As required by law, the final rule revises the APC groups to take into account drugs and devices that no longer qualify for pass-through status, new and deleted HCPCS/CPT codes, changes in technologies, new services, and new cost data. In addition, the final rule includes input from the Advisory Panel on APC Groups (APC Panel)—an outside panel of experts established by the Balanced Budget Act (BBA) of 1997.

A complete discussion of APC group changes can be found on the *Federal Register* pages referenced above. In the final rule for CY 2009, CMS made significant changes to several status codes that are reflected below. This summary shows the APCs per category for services other than pass-throughs.

APC Category	Status Indicator	Status			
		2006	2007	2008	2009
Clinic or Emergency Department Visit	V	6	10	12	16
Significant Procedures, Multiple Reduction Applies	T	208	213	188	183
Significant Procedures, No Multiple Reduction	S	128	144	128	130
Ancillary Services	X	46	45	39	40
Pass-Through Devices Categories	H	55	43	2	8
Non-Pass-Through Drugs/Biologicals	K	292	306	324	275
Partial Hospitalization	P	1	1	2	2
Observation	Q	1	1	0	0
Blood and Blood Products	R		Included in K		25
Brachytherapy Sources	U		Included in K		16
New Technology	S/T	82	81	82	82
<b>Total</b>		<b>819</b>	<b>844</b>	<b>777</b>	<b>777</b>

**CMS' Proposal:** For CY 2009, CMS proposed “. . . that status indicator “R” would be assigned to blood and blood products; status indicator “U” would be assigned to brachytherapy sources . . . .”

**CMS' Final Rule:** CMS is finalizing its proposal without modification for CY 2009.

## VIII. Other

### Clinic Visits, ED Visits, and Critical Care Services

*Federal Register* pages 68676 - 68694

Currently, CMS instructs hospitals to report visit HCPCS codes for three types of OPPS services: clinic visits, emergency department (ED) visits, and critical care services. However, CMS believes that CPT Evaluation and Management (E/M) codes were defined to reflect the activities of physicians and do not describe well the range and mix of services provided by hospitals during visits of clinic and ED patients and critical care encounters.

#### Visit Reporting Guidelines

Currently, there is no national policy to determine the assignment of E/M codes. Hospitals are required to report facility resources for clinic and emergency department visits using CPT E/M codes and to develop internal hospital guidelines to determine what level of visit to report for each patient. While national guidelines are being developed, CMS has advised that each hospital's internal guidelines should follow the intent of the CPT code descriptors, in that the guidelines should be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the codes.

CMS will **not** implement national guidelines prior to CY 2010.

#### Clinic Visits, New and Established Patient Visits

In determining a definition to distinguish between a “new” and “established” patient visit, CMS in the CY 2000 final rule adopted the CPT definition which states that an “established” patient is “one who has received professional services from the physician or another physician of the same specialty who belongs to the same group practice, within the past three years” and has a hospital medical record number. Otherwise, the patient would be considered “new.” However, over the past year, CMS has heard from several providers

that based on the above definition it is difficult to distinguish between “new” and “established” for purposes of reporting clinic visits correctly.

**CMS’ Proposal—Clinic Visits, New and Established Patient Visits:** For CY 2009, CMS proposed “. . . to modify the definitions of “new” and “established” patients as they apply to hospital outpatient visits. Specifically, the meanings of “new” and “established” would pertain to whether or not the patient was registered as an inpatient or outpatient of the hospital within the past three years. Under this proposal, hospitals would not need to determine the specific clinic where the patient was previously treated because the proposed approach would not rely upon when the medical record was initially created but rather, would depend upon whether the individual had been registered as a hospital inpatient or outpatient within the previous three years.”

**CMS’ Final Rule:** CMS is finalizing its proposal without modification for CY 2009.

### **Type B Emergency Department (ED) Visits**

“Type B” EDs offer emergency level services but are not open “24/7.” As of CY 2007, these services were reported using five specific G-codes and paid based upon clinic APCs. The G-codes would serve as a means to distinguish between a Type B ED from a Type A ED (ED that must be available to provide services 24/7 and meet one or both of the EMTALA requirements). After two years of implementation of the G-codes for the Type B EDs, CMS now has cost data available to adjust charges appropriately to reflect differences between a Type B ED and a Type A ED.

**CMS’ Proposal—Type B ED Visits:** For CY 2009, CMS proposed “. . . to pay levels 1, 2, 3, and 4 Type B emergency department visits through four levels of newly created APCs, 0626 (Level 1 Type B Emergency Visits), 0627 (Level 2 Type B Emergency Visits), 0628 (Level 3 Type B Emergency Visits), and 0629 (Level 4 Type B Emergency Visits). We are proposing to assign HCPCS codes G0380, G0381, G0382, and G0383, the levels 1, 2, 3, and 4 Type B emergency department visit Level II HCPCS codes, to APCs 0626, 0627, 0628, and 0629, respectively, for CY 2009. These HCPCS codes would be the only HCPCS codes assigned to these newly created APCs.”

**CMS’ Final Rule:** CMS is finalizing its proposal without modification for CY 2009.

### **Partial Hospitalization**

*Federal Register* pages 68694 - 68702

**Background:** Partial hospitalization is an intensive outpatient psychiatric program provided to patients in place of inpatient psychiatric care. A partial hospitalization program (PHP) may be provided by a hospital to its outpatients or by a freestanding Community Mental Health Center (CMHC). Under the OPPTS, providers are paid on a per diem basis for partial hospitalization services.

Generally, CMS is required to establish relative payment weights based on median costs. Historically, the median per diem cost for CMHCs has greatly exceeded the median per diem cost for hospital-based PHPs. CMS indicates that hospital-based PHPs are Medicare providers that are required to maintain uniform charges for all payers and therefore are less likely to significantly change their charges for PHP from year to year, while many CMHCs have indicated that Medicare is their only payer and as a result may have increased and decreased their charges in response to Medicare payment policies, including the manipulation of charges to inappropriately receive outlier payments. As a result, there has been a significant fluctuation in the CMHC median per diem costs over the past few years, while hospital-based median per diem costs have remained relatively stable.

**CMS’ Proposal:** For CY 2009, CMS proposed to create two new APCs for PHPs to more accurately reflect service intensity.

“ . . . we believe that programs that provide four or more services should be paid an amount that recognizes that they have provided a more intensive day of care. Accordingly, as there are circumstances when three services provided may be appropriate, but to reflect our general belief that the data trend that four or more services more appropriately indicated the comprehensive nature of PHP services, for CY 2009, we are proposing to create two separate APC payment rates for PHP:”

<b>Proposed APC</b>	<b>Group Title</b>	<b>Proposed Per Diem Rate</b>
0172	Level I Partial Hospitalization (3 services)	\$140
0173	Level II Partial Hospitalization (4 or more services)	\$174

In addition, CMS proposed to deny payment for low-intensity days. “In conjunction with and to conform to our proposed CY 2009 PHP per diem rates that account for a minimum of three units of service provided, . . . we are proposing to deny payment for any PHP claims for days when fewer than three therapeutic services are provided. We believe that three services should be the minimum number of services allowed in a PHP day because a day with one or two services does not meet the statutory intent of a PHP program.”

**CMS’ Final Rule:** For CY 2009, CMS is finalizing their “...two-tiered payment rates as proposed, but are instead using hospital-based PHP data only to calculate the two per diem payment rates.”

The two new APC’s for PHP are shown below.

<b>Final APC</b>	<b>Group Title</b>	<b>Final Per Diem Rate</b>
0172	Level I Partial Hospitalization (3 services)	\$157
0173	Level II Partial Hospitalization (4 or more services)	\$200

In addition, CMS will deny payment for low-intensity days as they will require a minimum of 20 hours of service per week for patients to be eligible for PHP.

## **Inpatient-Only Procedures Payment**

*Federal Register* pages 68698 - 68702

**Background:** CMS identifies procedures that are typically provided only in an inpatient setting, and therefore would not be paid by Medicare under the OPPS. These procedures comprise what is referred to as the “inpatient only list.” The inpatient-only list specifies those services that will only be paid when provided in an inpatient setting because of the nature of the procedure and the need for at least 24 hours of post-operative recovery time or monitoring before the patient can be safely discharged. These procedures are assigned a status code of “C” and hospitals are advised to admit beneficiaries requiring these procedures to receive payment. Each year, CMS, with input from the APC Panel, reviews the inpatient only list using specific criteria to determine whether any procedures should be moved from the inpatient only list and assigned to an APC.

**CMS’ Proposal:** “. . . we are proposing that 11 procedures be removed from the OPPS inpatient list for CY 2009 and be assigned to clinically appropriate APCs . . . .”

**CMS’ Final Rule:** CMS is removing 12 CPT codes from the inpatient list.

For a complete list of the 12 procedures removed from the inpatient-only list refer to Table 39 on *Federal Register* page 68701.

## Devices Replaced with No Cost or Hospital Receives Credit

*Federal Register* pages 68629 - 68632

**Background:** In recent years, there have been several field actions and recalls with regard to failure of implantable devices. In many of these cases, the manufacturers have offered replacement devices without cost to the hospital or with credit for the device being replaced if the patient required a more expensive device.

For CY 2007, CMS implemented a policy that reduced the payment for select device-dependent APCs when the hospital receives certain replacement devices without cost or receives a full credit for the device being replaced. This policy did not apply to cases in which there was a partial credit toward the replacement of the device.

In CY 2008, CMS expanded the policy to include cases in which hospitals receive partial credits of 50 percent or more of the cost of a specified device. Starting in CY 2008, hospitals were required to add the “FC” modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new devices. In addition, when a specified device code is present on the claim and the procedure code maps to a specific APC, the OPSS payment is reduced by 100 percent of the device offset for full credit or no cost cases and 50 percent for partial credit cases.

**CMS’ Proposal:** For CY 2009, CMS proposed “. . . to continue the policy of reducing OPSS payment by 100 percent of the device offset amount when a hospital furnishes a specialized device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost of the device.”

In addition, CMS is “. . . proposing to continue using the three criteria established in the CY 2007 OPSS/ASC final rule with comment period for determining the APCs to which this policy applies . . . . Specifically,

- (1) all procedures assigned to the selected APCs must require implantable devices that would be reported if device insertion procedures were performed,
- (2) the required devices must be surgically inserted or implanted devices that remain in the patient’s body after the conclusion of the procedures (at least temporarily), and
- (3) the device offset amount must be significant, which for purposes of this policy is defined as exceeding 40 percent of the APC cost.”

Furthermore, for CY 2009, “. . . we are proposing to add APC 0425 . . . and APC 0648 . . . and their associated devices that would not otherwise be on the device list for CY 2009 . . . . We also are proposing to remove APC 0106 . . . and device HCPCS codes associated only with procedures assigned to this APC . . . .”

**CMS’ Final Rule:** CMS is finalizing their CY 2009 proposal, except they are **not** implementing their proposal to remove APC 0106.

Table 21 of the *Federal Register* on page 68631 lists the APCs impacted and the device offset amounts applicable in cases of no cost or full or partial credit for replaced devices for CY 2009.

## Beneficiary Copayments

*Federal Register* pages 68600 - 68601

**Background:** The BBRA requires rules for determining copayment amounts to be paid by beneficiaries for covered outpatient department (OPD) services. The national unadjusted copayment amount for a covered OPD service provided in a year must be reduced so that the effective copayment rate for that service does not exceed a specified percentage. For all services under the OPSS in CY 2009, and in subsequent years, the

percentage is 40 percent of the APC payment rate. In addition, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount.

**CMS' Final Rule:** For CY 2009, *“...the Medicare beneficiary’s minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would equal the product of the reporting ratio and the national unadjusted copayment or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.”*

The national unadjusted copayment amounts for services payable under the OPPS that will be effective January 1, 2009 are shown in Addendum A and B of the final rule.